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(56) Documents cited

GB 1539771

GB 1398253

GB 827331

GB 462977

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(54) Dermatological compositions
containing hydrogen peroxide

(57) A dermatological composition,
for treating skin conditions such as
acne contains hydrogen peroxide
buffered to a pH of less than 7 in
the form of a non-greasy single
phase aqueous gel. The buffer may
be selected from lactic acid, citric
acid, tartaric acid, maleic acid, hy-
droxysuccinic acid, potassium acid
phosphate, sodium and potassium
acid citrate and sodium and potas-
sium acid tartrate.

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SPECIFICATION

D rmatological compositions

5 The invention relates to d rmatological compositions containing hydrogen peroxide. The invention is primarily concerned with such compositions for human therapeutic use. It is however to be understood that the invention is not intended to be limited to such use and thus for example compositions according to the invention may be used in a veterinary rather than a human context and/or may be of cosmetic rather than therapeutic effect.

10 Hydrogen peroxide has a well-known therapeutic and cosmetic effect in a dermatological context due to its ability to make available free oxygen in contact with the skin. Further, hydrogen peroxide is a readily available and relatively inexpensive substance which need only be used in small quantities for dermatological purposes due to the high proportion of available oxygen which it contains. In these respects therefore hydrogen peroxide is a desirable substance for dermatological use. In other respects, however, hydrogen peroxide has disadvantages, in particular due to the fact that the substance is very unstable, due to the possible damage to skin tissue which may be caused if the skin is exposed to an unduly large amount of hydrogen peroxide, and due to the fact that hydrogen peroxide had a high surface tension and therefore tends not to spread easily on the skin and make intimate contact therewith.

15 In our prior Patent 1,539,771, there is disclosed a dermatological composition containing hydrogen peroxide with which the above-mentioned disadvantages can be avoided or at least appreciably reduced. More specifically, said prior Patent describes a dermatological composition in the form of a cream, lotion or gel comprising an oil medium dispersed in an aqueous medium, said aqueous medium containing hydrogen peroxide and a buffer to maintain the pH of the composition at less than 7.

20 The object of the present invention is to provide further improved dermatological compositions containing hydrogen peroxide.

25 According to the invention therefore there is provided a dermatological composition in the form of a single phase aqueous gel containing hydrogen peroxide and a buffer to maintain the pH of the composition at less than 7.

30 With this composition, due to the incorporation of the hydrogen peroxide in an aqueous gel preparation and due to the presence of the acid buffer it is possible to achieve surprisingly good dermatological activity with a relatively small proportion of hydrogen peroxide whereby the possibility of damage to the skin tissue can be avoided or at least appreciably minimised, and also it is possible to achieve a remarkable stability to the extent that such

35 dermatological activity can be expected to be retained after an appreciable period of storage. The use of hydrogen peroxide in an aqueous gel also enables easy and intimate application to the skin.

40 In accordance with a preferred embodiment of the invention, the said single phase is non-lipid, and the composition is of the 'vanishing' kind and is free of all waxes, fats and oils.

45 Such composition when applied to the skin does not have an oily or greasy feel and is therefore particularly suitable for treating distressing skin conditions such as acne.

50 With regard to the buffer, this is preferably such as to maintain the pH at 2.5 to 6.5, particularly 2.5 to 3.2, and any suitable system may be used for this purpose. Thus, for example, there may be used an acid such as lactic acid, citric acid, tartaric acid, maleic acid, hydroxysuccinic acid with an acid salt. Said acid salt may be any of sodium and potassium acid phosphate, sodium and potassium acid citrate, sodium and potassium acid tartrate.

55 Preferably the composition of the invention also incorporates a water-miscible volatile organic solvent. Such solvent may be an alcohol particularly an alkyl alcohol having 1 to 3 carbon atoms (especially ethanol). Alternatively a ketone, particularly acetone may be used. The solvent can provide cleansing antiseptic and drying properties on the skin, and also can facilitate gel formation and water miscibility of other ingredients.

60 In order to achieve and maintain a stable gel structure, the composition may incorporate one or more gelling or thickening agents. Suitable substances include the following: carboxy vinyl polymer (carboxy polymethylene), colloidal magnesium aluminium silicate, colloidal magnesium silicate, natural gums, starch (modified or unmodified and from various sources), cellulose derivatives (particularly hydroxy propylmethyl cellulose). In a particularly preferred embodiment a mixture of colloidal magnesium silicate and hydroxy propylmethyl cellulose is used.

65 Further, and in order to facilitate intimate contact between the hydrogen peroxide and the skin, the composition may incorporate a surface active agent which is soluble in the said single phase. Such surface agent is most preferably a non-ionic substance particularly polyoxyethylene 23 lauryl ether or polyoxyethylene 4 lauryl ether, although other surfactants (preferably but not necessarily polyoxyethylene or polyoxypropylene derivatives) may be used.

70 If desired, a humectant, such as propylene glycol, may be incorporated in the composition.

75 The composition of the invention may be manufactured by appropriate mixing of the ingredients with stirring and/or heating as required.

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The above ingredients may be incorporated in the following proportions (all percentages being by weight):

- Hydrogen peroxide 0.75%–3.75%, preferably 0.75%–2% particularly 1.5% (based on 100% hydrogen peroxide although in practice hydrogen peroxide in say 30% aqueous solution may be used).
Solvent 1%–50%. Preferably 40% in the case of ethanol, 10% in the case of acetone.
Gelling Agent 0.1%–7.5% (for each in the case where two substances are used in combination, a preferred combination being 1% hydroxypropyl methyl cellulose and 1% colloidal magnesium silicate).
Buffer system as required, say 0.5% acid salt with 0.5% acid.
Surfactant 5%–15% preferably 6%.
Humectant 2%–10% preferably 5%.
Water 10–80% preferably about 45%.

Of course, the invention is not restricted to the above seven ingredients: some of these may be omitted and others may be added.

- In accordance with one Example of the invention, the following ingredients and proportions are used (all percentages being by weight):

Hydrogen peroxide	1.5%
Ethanol	40%
Hydroxypropyl methyl cellulose	1%
Colloidal magnesium silicate	1%
Sodium acid phosphate	0.5%
Lactic acid BP	0.5%
Polyoxyethylene 23 lauryl ether	6%
Propylene glycol	5%
Water	44.5%

This Example composition has good stability and is an effective and cosmetically acceptable preparation for use in the treatment of acne. It is of course to be understood that the invention is not intended to be restricted to the ingredients or proportions of the Example composition and, in addition it is to be appreciated that a composition according to the invention need not be used for the treatment of acne but may be used for the treatment of burns or for the treatment of any other suitable human or animal skin condition or for any other suitable dermatological purpose.

CLAIMS

1. A dermatological composition in the form of a single phase aqueous gel containing hydrogen peroxide and a buffer to maintain the pH of the composition at less than 7.
2. A composition according to claim 1, which is free of all waxes, fat and oils, said single phase being non-lipid.
3. A composition according to claim 1 or 2, which is buffered to a pH of 2.5 to 6.5.

4. A composition according to claim 3, wherein the pH is 2.5 to 3.2.

5. A composition according to any one of claims 1 to 4 wherein the buffer comprises an acid mixed with an acid salt.

6. A composition according to claim 5, wherein the acid is selected from lactic acid, citric acid, tartaric acid, maleic acid, hydroxy-succinic acid, and the acid salt is selected from sodium and potassium acid phosphate sodium and potassium acid citrate and sodium and potassium acid tartrate.

7. A composition according to any one of claims 1 to 6, further including a water-miscible volatile organic solvent.

8. A composition according to claim 7, wherein the solvent is an alcohol.

9. A composition according to claim 8, wherein the alcohol has 1 to 3 carbon atoms.

10. A composition according to claim 7, wherein the solvent is a ketone.

11. A composition according to claim 10, wherein the ketone is acetone.

12. A composition according to any one of claims 1 to 11, incorporating one or more gelling or thickening agents selected from: carboxy vinyl polymer, colloidal magnesium aluminium silicate, colloidal magnesium silicate, natural gums, starch, cellulose derivatives.

13. A composition according to claim 12, incorporating as a gelling or thickening agent a mixture of colloidal magnesium silicate and hydroxy propylmethyl cellulose.

14. A composition according to any one of claims 1 to 13, further including a surface active agent.

15. A composition according to any one of claims 1 to 14, further including a humectant.

16. A composition according to any one of claims 1 to 15, containing 0.75%–3.75% by weight hydrogen peroxide.

17. A composition substantially as hereinbefore described in the Example.

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